K083495

MAR 2 4 2009

510 (k) Summary
for N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) and N/T Protein Control LC

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

1. Manufacturer's Name, Address, Telephone, and Contact Person,

Manufacturer: Siemens Healthcare Diagnostics Products GmbH
Emil-von-Behring Str. 76
35041 Marburg, Germany

Contact Information:
Helen M. Lee
Siemens Healthcare Diagnostics
Glasgow Business Community
500 GBC Drive M/S 514
Newark, DE 19714-6101
302.631.8706
302.631.6299 (fax)

Date of Preparation: November 6, 2008

2. Name of Product:

N Antisera to Human Immunoglobulins (IgG, IgA, and IgM)
N/T Protein Control LC

Class: Immunological Test System; Quality Control Material, CLASS II
21 CFR 866.5510
Panel: IMMUNOLOGY
Product Code: CFN

3. Identification of the Legally Marketed Device:

Beckman Coulter IMMAGE® Immunochemistry Systems Urine Immunoglobulin G (IGU) k951635.

Dimension Vista® Protein 3 Control k072435

4. Device Descriptions:

N Antisera to Human Immunoglobulins (IgG, IgA, and IgM)

Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

N/T Protein Control LC

The N/T Protein Control LC is a multi-analyte, lyophilized, polygeline and rabbit albumin based product.

5. Device Intended Uses:

N Antisera to Human Immunoglobulins (IgG, IgA, and IgM)

In vitro diagnostic reagents for the quantitative determination of immunoglobulins (IgG, IgA and IgM) in human serum, heparinized and EDTA plasma, and IgG in human urine and cerebrospinal fluid (CSF) by means of immunonephelometry on the BN™ Systems. Measurement of immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

N/T Protein Control LC

N/T Protein Control LC is intended for use as an assayed intralaboratory quality control for assessment of precision and analytical bias in immunochemical determination of the proteins IgG in CSF, IgA in CSF, IgM in CSF; IgG in urine, transferrin in urine, albumin in urine and CSF, α1-microglobulin in urine and total protein in urine and CSF using the BN™ Systems.

6. Medical Device to which equivalence is claimed and comparison information:

The IMMAGE® Immunochemistry System Urine Immunoglobulin G (IGU) was determined to be substantially equivalent in 510 (k) Premarket Notification k963974 and is the predicate for adding the urine sample matrix to the N Antisera IgG assay.

Method Comparison Data

Protein		Coefficient of Correlation
IgG	y = 0.926 x - 0.34 mg/L	0.99

The current N Antisera to Human Immunoglobulins (IgG, IgA, and IgM) was determined to be substantially equivalent in 510 (k) Premarket Notification k042735. The operating principle and reagent composition have not changed. For your convenience, the sections with changes have been underlined in the Draft Instructions for Use included in this submission.

The Dimension Vista® Protein 3 Control (k072435) is the predicate for adding the urine sample matrix to the N/T Protein Control LC. The modified N/T Protein Control LC, like the predicate is intended to be used as an assayed accuracy and precision control for Immunoglobulin G in urine.

7. Conclusion:

The studies included in this submission demonstrate correlation to and equivalent performance between the predicate IMMAGE® IGU assay and the N Antisera to Human IgG urine assay.

The N/T Protein Control LC, modified to include IgG urine values, is substantially equivalent in Intended Use to the Dimension Vista® Protein 3 Control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 4 2009

Siemens Healthcare Diagnostics, Inc
c/o Ms. Helen M. Lee
Regulatory Affairs and Compliance Manager
500 GBC Drive, M/S 514
Newark, DE 19714

Re: k083445
Trade/Device Name: N Antisera to Human Immunoglobulins (IgG, IgA, and IgM)
Regulation Number: 21 CFR § 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system
Regulatory Class: Class II
Product Code: CFN, JJY
Dated: February 12, 2009
Received: February 13, 2009

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Maria Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K083445

Device Name: N Antisera to Human Immunoglobulins (IgG, IgA, and IgM)

Indication For Use:

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Prescription Use __X__ And/Or Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K083445

Indication for Use

510(k) Number (if known): K083445

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Indication For Use:

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Prescription Use _X_____ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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